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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/017,273	12/12/2001	Alasdair Mark Naylor	PC22013AADO	7030

7590

07/08/2004

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EXAMINER

HUI, SAN MING R

ART UNIT

PAPER NUMBER

1617

DATE MAILED: 07/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action**

Application No.

10/017,273

Applicant(s)

NAYLOR ET AL.

Examiner

San-ming Hui

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--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 09 June 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY** [check either a) or b)]

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on \_\_\_\_\_. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will not be entered because:
- (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see Note below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See attachment.

3. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See attachment.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☒ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: None.

Claim(s) objected to: None.

Claim(s) rejected: 3-9, 13-16, 24, 33-38, and 44.

Claim(s) withdrawn from consideration: 11, 17-23, 25, 28-32 and 39-43.

8. ☒ The drawing correction filed on 29 May 2002 is a) ☒ approved or b) ☐ disapproved by the Examiner.
9. ☒ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). June 9, 2004
10. ☐ Other: \_\_\_\_\_

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### **ADVISORY ACTION**

Continuation of 2):

Applicant's proposed amendments filed June 9, 2004 raised new issue for the Examiner. The newly recited limitation in claim 15, "having systemic selectivity of NPY receptors associated with the male genitalia..." raised new issue and consideration for the Examiner. It is not clear what the term "systemic selectivity" would refer to. Does the NPY inhibitor have a systemic selectivity of NPY in the whole body or specific selectivity of NPY in the male genitalia? The term "systemic" usually means something that is pertaining to the whole system rather than to a specific local sites. In the instant claim, the applicant apparently means specific selectivity to NPY in male genitalia for sexual dysfunction therapeutic effect.

Continuation of 5):

Applicant's arguments filed June 9, 2004 averring the rejections under 35 USC 112, second paragraph being moot in view of the proposed amendments have been considered, but are not found persuasive. The rejections under 35 USC 112, second paragraph remain since the proposed amendments filed June 9, 2004 will not be entered.

Applicant's arguments filed June 9, 2004 averring Gregor's failure to teach F50 as an NPY inhibitor and therefore, concluding the cited prior's insufficiency to provide motivation to combine the teachings of cited prior art have been considered, but are not found persuasive. Examiner notes that the instant claims recite the employment of an

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NPY inhibitor, in which F50 happens to be one of the compounds herein, to treat MED.

Gregor teaches that the compounds therein, wherein F50 is one of them, as useful being a vasodilating agents to treat sexual dysfunction.

Applicant's arguments filed June 9, 2004 averring Hutchison's teaching with regard to the NPY inhibitors as vasodilator of penile veins have been considered, but are not found persuasive. Such arguments been addressed in the previous office action mailed April 7, 2004. Furthermore, Applicant argues that one of ordinary skill in the art would not expect the inhibition of NPY would result in the vasodilation of penile veins. Examiner notes that Argiolas (provided by the applicant along with the response filed June 9, 2004) teaches that the effect of NPY on penile arteries as contraction. And therefore, the inhibition of NPY would reasonably expected to be relaxation, i.e., dilation of penile arteries (See Argiolas, page 240, Table 3). When taken the teachings of prior art as a whole, the NPY inhibitors are useful as vasodilators which would increase the blood reperfusion to organs. Therefore, one of ordinary skill in the art, possessing the teachings of the cited prior art, would therefore, reasonably expect the inhibition of NPY would lead to vasodilation and blood flow to the penile tissue.

Applicant's arguments filed June 9, 2004 with regard to the teachings of Harrison have been considered, but are not found persuasive. Examiner notes that the applicant actually did not point out if there is any flaw in the teachings of Harrison. Moreover, this is not just "an interesting speculative theory" as categorized by the applicant, but a well-known mechanism of erection maintenance in the art as taught in a basic medical textbook. Applicant further argues, by citing Argiolas, page 241, col. 1, teaching "the

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potentiation of sympathetic tone ... Therefore, it is possible that NPY has a role in the maintenance, if not in the induction of penile erection", that "the venal occlusion, resulting from the compression of the venules against the tunica albuginea may not be sufficient to obtain rigidity and may require secondary activities to provide optimum venal occlusion". Such arguments have been considered, but are not found persuasive. The teachings of Argiolas are not seen to be contradicting to what Examiner set forth in the previous office action. In fact, they compliment what the Examiner set forth in the previous office action. NPY induced vasocontraction is apparently through the potentiation of Noradrenaline-induce vasocontraction activities. Therefore, by inhibiting NPY, the relaxation of penile arteries would be reasonably expected, and thus, causing vasodilatation of penile arteries and increasing blood flow to the cavernosal smooth muscle, which in turn, causing erection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming Hui whose telephone number is (571) 272-0626. The examiner can normally be reached on Mon 9:00 to 1:00, Tu - Fri from 9:00 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, PhD., can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

San-ming Hui  
Patent Examiner  
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A handwritten signature in black ink, appearing to read 'San-ming Hui', is positioned below the printed name and title.